



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5707

September 7, 2006

ADVERSE DETERMINATION LETTER

BY FACSIMILE &
CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. John F. McGuire
Executive Vice President
Biomedical Services
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

RE: *United States v. American National Red Cross*, Civil Action No. 903-0949 (JGP)

Dear Mr. McGuire:

Paragraph X of the Amended Consent Decree of Permanent Injunction (Decree) entered on April 15, 2003 permits the Food and Drug Administration (FDA) to assess a penalty for "each unit of unsuitable blood or blood component that [the American Red Cross (ARC)] distributes after entry of [the Decree] for which FDA determines that the release was preventable by ARC...." Paragraph X.A.2. of the Decree provides that "[i]f FDA determines that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote, FDA may assess a penalty of up to \$5,000 for each such unit of blood or each such blood component. Notwithstanding the foregoing, FDA shall not assess ARC under this subparagraph (X.A.2) for the improper release of more than 100 units in any one event."

FDA has recently completed a review of its database and files to identify classified¹ recalls conducted by ARC. We identified 165 events in which ARC reported to FDA that it retrieved unsuitable blood components that were distributed during the period of April 15, 2003 through April 15, 2005 (this does not include any classified ARC-conducted recalls previously identified in the May 15, 2005 adverse determination letter). FDA determined that these events were preventable by ARC, that they meet the health hazard criteria of paragraph X.A.2. of the Decree, and that no penalty exception listed in Paragraph X.B. of the Decree applies. These events involved 12,233 unsuitable blood components.

¹ Recall classifications are numerical designations assigned by FDA to indicate the relative degree of health hazard presented by the recalled product. 21 C.F.R. § 7.3(m).

Seven of the events involved more than 100 unsuitable blood components but were limited for penalty purposes to 100 units as provided by Paragraph X.A.2. of the Decree. The total number of unsuitable blood components for which FDA assessed a penalty under Paragraph X.A.2. of the Decree is 1083.

The unsuitable blood components are listed by event in the attachment to this letter. The events are identified by ARC-assigned biological product deviation numbers and FDA-assigned recall numbers and are arranged by ARC regions. The attached list does not include all events that occurred during the specified time period; it includes only those events classified by FDA as of May 1, 2006. After FDA review, additional penalties may be assessed for events that occurred during the aforementioned time period but are not listed in the attachment.

Paragraph X.A.2. of the Decree sets forth three factors FDA must consider when determining whether to assess a penalty and the amount of a penalty: "(1) the potential effect of the event on the public health, e.g., the number and seriousness of exposures; (2) ARC's trends with respect to the same or similar events involving the release of unsuitable products; and (3) the degree to which ARC contributed to the improper release of the blood or blood components." FDA has considered these factors and has assessed penalties accordingly for each unsuitable blood component (see attached list). The total penalty is \$4,224,000.

As provided in the Decree, if ARC agrees with this adverse determination, it must, within 20 days of receipt of this letter, notify FDA of its intent to come into compliance with the Decree, submit a plan to do so, and pay the penalty no later than thirty days (30) thereafter. If ARC disagrees with FDA's adverse determination, it shall respond in writing within 20 days of receipt of this letter, explaining the reason(s) for disagreeing with FDA's determination. The response must be submitted to me at the Food and Drug Administration, Baltimore District Office, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, with a copy to Jesse Goodman, M.D., M.P.H., Director, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200N, Rockville, Maryland 20852.

Sincerely yours,



Evelyn Bonnin
Director, Baltimore District

Attachment

cc: Mr. John F. McGuire
Interim President and CEO
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

C. William Cherry
Senior Vice President for Quality
and Regulatory Affairs
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

**Mary Elcano
General Counsel
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006**

**Bonnie McElveen-Hunter
Chairman, Board of Governors
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006**

AMERICAN RED CROSS

CLASS II RECALLS FOR THE PERIOD 4/15/03 THROUGH 4/15/05 (EXCLUDING THOSE PREVIOUSLY ADDRESSED IN THE MAY 15, 2005 PARAGRAPH X ADVERSE DETERMINATION LETTER)

The following regions have no recall information included in this report:

Alabama Region, FDA Registration 1073001
Central Plains, Wichita, KS, FDA Registration 1973042
Gulf Coast, Mobile, AL, FDA Registration 1073005
Midwest, Omaha, NE, FDA Registration 1973037
Northern California, Oakland, CA, FDA Registration 2971430
Puerto Rico, Rio Piedras, PR, FDA Registration 2675945
Tennessee Valley, Nashville, TN, FDA Registration 1073006

<u>Region/CFN</u>	<u>Biological Product Deviation Number/ Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
Appalachian 1173010	2004-035-0621471 B-2423-5	1 - Red Blood Cells	Failure to control suspect blood component(s) (inappropriate release-enzyme immunoassay (EIA) positive hepatitis B core)	\$5,000	\$5,000
Arizona 2072997	2004-007-0416380 B-1480-5	1 -Red Blood Cells Leukocytes Reduced Irradiated	Component preparation (discrepant irradiation times documented)	\$3,000	\$3,000
	2004-007-0575401 B-0390-5	6 -Platelets Pheresis Leukocytes Reduced	Component preparation (no confirmation of leukocyte reduction)	\$4,000	\$24,000
	2004-007-0649384 B-1763-5	1 -Platelets Pheresis Leukocytes Reduced Irradiated	Donor eligibility (Blood Donation Record (BDR) question unanswered)	\$3,000	\$6,000
Badger-Hawkeye 2173028	B-1764-5 2003-03-20217889 B-1676-4 B-1677-4 B-1678-4	1 - Fresh Frozen Plasma Pheresis 1 - Platelets Leukocytes Reduced 1 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor eligibility (failure to defer donor for increased risk of infection with hepatitis)	\$4,000	\$12,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
Carolinias Region 1073007	2004-012-0715488 B-0999-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2004-012-0505489 B-1019-5 B-1020-5	3 - Red Blood Cells Leukocytes Reduced 1 - Plasma Frozen	Donor eligibility (failure to follow standard operating procedures (SOPs) for donors unable to answer health questions on their own)	\$2,000	\$8,000
	2003-012-0122163 B-2381-5	1 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2003-012-0176772 B-1201-5	1 - Red Blood Cells Leukocytes Reduced	Testing (sample tube mislabeling mix-up)	\$5,000	\$5,000
	2003-012-0210391 B-0078-6	3 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$12,000
	2004-012-0343049 B-1953-5	1 - Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (unit not placed on hold when deviation on BDR was found)	\$5,000	\$5,000
	2004-012-0370556 B-0715-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2004-012-0378599 B-2382-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2004-012-0379026 B-2380-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2004-012-0398025 B-0931-6 B-0932-6	1 - Red Blood Cells Leukocytes Reduced 1 - Recovered Plasma	Failure to control suspect blood component(s) (inappropriate release of products from a deferred donor)	\$5,000	\$10,000
	2004-012-0456922 B-0888-6	1 - Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (products were not discarded after discovery of an error on the BDR)	\$5,000	\$5,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/ Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	2004-012-04868895 B-0887-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in a malaria risk area)	\$4,000	\$4,000
	2004-012-0544145 B-0716-6	2 - Red Blood Cells Pheresis Leukocytes Reduced	Donor eligibility (travel to malaria risk area)	\$4,000	\$8,000
	2004-012-0559097 B-0860-6	1 - Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (intended for validation study)	\$5,000	\$5,000
	2004-012-0577082 B-0885-6 B-0886-6	1 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor eligibility (BDR question related to Creutzfeldt Jakob Disease (CJD) was unanswered)	\$4,000	\$8,000
	2004-012-0589867 B-2384-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in a malaria risk area)	\$4,000	\$4,000
	2004-012-0603330 B-0175-6	1 - Platelets Pheresis Leukocytes Reduced	Component preparation (platelet yield too high for storage in a single bag)	\$4,000	\$4,000
	2004-012-0631857 B-0738-6	1 - Platelets Pheresis Leukocytes Reduced	Collection (failure to follow manufacturer's instructions)	\$3,000	\$3,000
	2004-012-0719187 B-0994-5	1 - Platelets Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (inappropriate release after noting discrepant information on the apheresis procedure record)	\$5,000	\$5,000
	2005-012-0810629 B-2026-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
	2005-012-0821156 B-1928-5	1 - Platelets Pheresis Leukocytes Reduced	Collection (failure to follow manufacturer's instructions)	\$3,000	\$3,000
	2005-012-0882462 B-0415-6	17 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$68,000
	2005-012-0931808 B-0452-6 B-0453-6	1 - Red Blood Cells Leukocytes Reduced 3 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$16,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/ Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	2004-012-0358460 B-0867-6 B-0868-6	7 - Red Blood Cells Leukocytes Reduced 4 - Red Blood Cells Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (units not placed on hold when deviation on BDRs were found)	\$5,000	\$145,000
	B-0869-6 B-0870-6	6 - Platelets Pheresis Leukocytes Reduced 4 - Platelets Pheresis Leukocytes Reduced Irradiated			
	B-0871-6 B-0872-6 B-0873-6	4 - Plasma Frozen Cryoprecipitate Reduced 2 - Cryoprecipitate AHF 4 - Recovered Plasma			
Central Ohio 1573013	2004-016-0431548 B-2005-4	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Failure to control suspect blood component(s) (inappropriate release after discovery of low platelet yield)	\$5,000	\$5,000
	2004-016-0449876 B-2012-4	2 - Red Blood Cells Leukocytes Reduced	Donor eligibility (quality control (QC) for Hemastat could not be verified)	\$3,000	\$6,000
Connecticut 1273014	B-0116-5	2 - Red Blood Cells Pheresis – Split Unit	Component preparation (failure to perform quality control testing)	\$3,000	\$6,000
	B-0541-5	1 - Red Blood Cells Pheresis	Failure to control suspect blood component(s) (low volume Red Blood Cells)	\$5,000	\$5,000
	B-1237-5 B-1238-5 B-1239-5 B-1240-5	2 - Red Blood Cells Leukocytes Reduced 2 - Platelets Leukocytes Reduced 2 - Fresh Frozen Plasma 2 - Recovered Plasma	Donor eligibility (travel in a CJD risk area)	\$4,000	\$32,000
Great Lakes 1873033	2004-018-0386370 B-1672-4	1 - Platelets Pheresis Leukocytes Reduced		\$5,000	\$5,000
	2004-018-0474355 B-0067-5 B-0068-5	1 - Red Blood Cells Leukocytes Reduced 1 - Recovered Plasma	Failure to control suspect blood component(s) (product intended for validation study)	\$5,000	\$10,000
	2004-018-0503561 B-0072-5 B-0073-5	1 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor eligibility (failure to follow up on medications taken by donor)	\$2,000	\$4,000
	2004-018-0631286 B-0549-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (hematocrit result was not documented)	\$3,000	\$3,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	2004-018-0687247 B-0595-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (hemoglobin was unsatisfactory and hematocrit not documented)	\$3,000	\$3,000
	2005-018-0751704 B-1112-5 B-1113-5	2 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor eligibility (failure to follow SOPs for travel outside the U.S.)	\$4,000	\$12,000
	2005-018-1081407 B-0587-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2005-018-1008818 B-0602-6	2 - Red Blood Cells Pheresis	Collection (sterility may have been compromised and failure to follow manufacturer's instructions)	\$5,000	\$10,000
Greater Alleghenies 2573016	B-0208-5	1 - Platelets Pheresis Leukocytes Reduced	Component preparation (failure to determine white blood cell count and failure to follow manufacturer's instructions)	\$4,000	\$4,000
	B-0209-5	2 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (failure to defer donor for taking Feldene)	\$2,000	\$4,000
	B-0904-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	B-0924-5	1 - Red Blood Cells Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (unit not tagged for hematocrit testing after device malfunction)	\$5,000	\$5,000
	B-1337-5 B-1338-5	1 - Red Blood Cells Leukocytes Reduced 1 - Cryoprecipitated AHF	Donor eligibility (failure to defer donor for taking Avodart)	\$5,000	\$10,000
	B-1396-5	1 - Platelets Pheresis Leukocytes Reduced	Component preparation (platelet yield too high for single bag)	\$4,000	\$4,000
	B-1890-5 B-1891-5 B-1892-5	2 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma 2 - Recovered Plasma	Donor eligibility (failure to defer donor for CJD risk)	\$4,000	\$20,000
	B-1944-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor who reported taking medication on the Medication Deferral List)	\$5,000	\$5,000

Region/CFN	Biological Product Deviation Number/ Recall Number	Number of Recalled Products/Product Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
	B-0320-6 B-0313-6 B-0317-6 B-0311-6 B-0314-6 B-0315-6 B-0318-6 B-0312-6 B-0316-6 B-0319-6 B-0321-6	1 - Red Blood Cells CPDA-1 for Manufacturing Non-Injectables Reduced 2 - Red Blood Cells Pheresis Leukocytes Reduced 3 - Liquid Plasma 2,121 - Red Blood Cells Leukocytes Reduced 278 - Platelets Leukocytes Reduced 1 - Platelet Pheresis Leukocytes Reduced 176 - Cryoprecipitated AHF 36 - Red Blood Cells Leukocytes Reduced Irradiated 332 - Fresh Frozen Plasma 44 - Plasma Cryoprecipitated AHF 1755 - Recovered Plasma	Donor eligibility (use of obsolete CJD information form)	\$4,000 for each of 100 blood components	\$400,000
Greater Chesapeake and Potomac 1173011	2004-053-0420855 B-0480-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR question pertaining to Avodart unanswered)	\$5,000	\$5,000
	2004-053-0571810 B-0763-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for taking Tazorac)	\$2,000	\$2,000
	2004-053-0560252 B-0765-5	3 - Platelets Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$12,000
	2004-053-0517279 B-0766-5	2 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$8,000
	2004-053-0580808 B-0841-5 B-0842-5	1 - Red Blood Cells Leukocytes Reduced 1 - Recovered Plasma	Donor eligibility (failure to defer donor for history of hepatitis)	\$4,000	\$8,000
	2004-053-0689598 B-1580-5 B-1581-5	1 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Failure to control suspect blood component(s) (quarantine error with overweight unit)	\$5,000	\$10,000
Greater Ozarks-Arkansas 2372998	2004-055-0413840 B-2020-5 B-2021-5	1 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor eligibility (failure to defer donor for hepatitis risk)	\$4,000	\$8,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	2003-055-0219886 B-2073-5	4 – Fresh Frozen Plasma	Failure to control suspect blood component(s) (inappropriate release after discovering clots in red blood cells)	\$5,000	\$20,000
	2003-055-0280152 B-2121-5	156 – Platelets Pheresis Leukocytes Reduced	Component preparation (failure to perform monthly QC for plateletpheresis products)	\$3,000 for each 100 blood components	\$300,000
	2003-055-0136101 B-2202-5	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (inappropriate release after reactive West Nile pool was reported)	\$5,000	\$5,000
	2005-055-0953356 B-0689-6 B-0691-6 B-0692-6	5 – Red Blood Cells Leukocytes Reduced 1 – Fresh Frozen Plasma 3 – Recovered Plasma	Donor eligibility (failure to defer donor for hepatitis risk)	\$4,000	\$36,000
Heart of America 1473043	2004-040-0643167 B-0465-5	1 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (sterility may have been compromised)	\$5,000	\$5,000
	2004-040-0642930 B-0466-5	3 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$12,000
	2004-040-0642994 B-0467-5	3 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$12,000
	2005-040-0804626 B-1327-5 B-1328-5	1 – Platelets Pheresis Leukocytes Reduced 1 – Platelets Pheresis Leukocytes Reduced Irradiated	Collection (failure to follow manufacturer's instructions)	\$3,000	\$6,000
	2005-040-0886454 B-1679-5	3 – Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to document the hematocrit reading)	\$3,000	\$9,000
	2005-040-1175515 B-0728-6	1 – Red Blood Cells	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/ Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
Indiana-Ohio 1873031	2005-038-0799491 B-1104-5	1 - Red Blood Cells	Failure to control suspect blood component(s) (inappropriate release after receiving post donation information)	\$5,000	\$5,000
	2004-038-0348688 B-1114-5 B-1115-5 B-1116-5 B-1118-5 B-1119-5 B-1120-5	4 - Red Blood Cells 189 - Red Blood Cell, Leukocytes Reduced 18 - Platelets 1 - Platelets Irradiated 30 - Fresh Frozen Plasma 141 - Recovered Plasma	Donor eligibility (use of obsolete SOP for CJD risk)	\$4,000 for each of 100 blood components	\$400,000
	2005-038-0867114 B-1815-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
Lewis and Clark 3072990	2003-020-0079860 B-0721-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (BDR question unanswered)	\$3,000	\$3,000
	2003-020-0221986 B-0211-6 B-0212-6 B-0213-6	2 - Fresh Frozen Plasma 1 - Plasma Cryoprecipitated Reduced 1 - Cryoprecipitated AHF	Failure to control suspect blood component(s) (inappropriate release after discovery of clots in red blood cells)	\$5,000	\$20,000
	2003-020-0279664 B-0630-6 B-0631-6	34 - Platelets Pheresis Leukocytes Reduced 5 - Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (failure to perform QC testing)	\$3,000	\$117,000
Mid-Atlantic 1173024	2004-029-0594370 B-0445-5	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (volume too great for one collection bag)	\$4,000	\$4,000
	2004-029-0606242 B-0461-5 B-0462-5	1 - Red Blood Cells Leukocytes Reduced 1 - Frozen Plasma	Donor eligibility (failure to defer donor for CJD risk)	\$4,000	\$8,000
	2004-029-0700521 B-1538-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/ Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
Missouri-Illinois 1973035	2005-011-0797069 B-0638-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (donor incorrectly removed from the National Donor Deferral Registry)	\$5,000	\$5,000
	2005-011-0793209 B-0684-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area) Collection (failure to follow manufacturer's instructions)	\$4,000 \$3,000	\$4,000 \$3,000
New England 1270026	B-1888-4	1 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	B-0501-5	1 - Red Blood Cells	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	B-0502-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
	B-0670-5	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Collection (sterility may have been compromised and failure to follow manufacturer's instruction)	\$5,000	\$5,000
	B-0723-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
	B-0947-5	2 - Platelets Pheresis Leukocytes Reduced	Collection (sterility may have been compromised and failure to follow manufacturer's instructions)	\$5,000	\$10,000
	B-0951-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	B-0956-5	1 - Red Blood Cells	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
	B-1006-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
	B-1007-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
	B-1009-5	1 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (failure to defer donor for taking Proscar)	\$5,000	\$5,000
	B-1023-5	1 - Fresh Frozen Plasma	Failure to control suspect blood component(s) (inappropriate release after discovery of clots in red blood cells)	\$5,000	\$5,000
	B-1996-5 B-1997-5	2 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor eligibility (failure to defer donor for taking Proscar)	\$5,000	\$15,000
	B-2005-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/ Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	B-0625-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malaria risk area)	\$4,000	\$4,000
New York- Penn 2438445	2004-001-0532479 B-2253-5 B-2254-5	1 - Red Blood Cells Leukocytes Reduced 1 - Recovered Plasma	Donor eligibility (failure to defer donor for hepatitis risk)	\$4,000	\$8,000
North Central 2173038	2003-017-0112629 B-0424-6	1 - Platelets Leukocytes Reduced	Donor eligibility (failure to defer donor for HIV risk) Component preparation (sterility may have been compromised)	\$5,000	\$5,000
	2003-017-0114568 B-0503-6	1 - Platelets Leukocytes Reduced	Failure to control suspect blood component(s) (overweight unit)	\$5,000	\$5,000
	2004-017-0320991 B-1097-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2004-017-0464920 B-1113-6	1 - Red Blood Cells Leukocytes Reduced	Component preparation (failure to assure leukoreduction)	\$4,000	\$4,000
	2004-017-0466796 B-1131-6	2 - Red Blood Cells Leukocytes Reduced	Donor eligibility (hemoglobin not documented)	\$3,000	\$3,000
Northeastern Pennsylvania 2573018	B-0069-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for urinary tract infection)	\$4,000	\$4,000
	B-0671-5	1 - Whole Blood	Collections (error on daily quality control record)	\$3,000	\$6,000
	B-0656-5	2 - Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (OC was not properly performed on the hematocrit centrifuge)	\$5,000	\$5,000
	B-1852-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to have a hematocrit value on the BDR)	\$3,000	\$3,000
	B-2375-5 B-2376-5	1 - Red Blood Cells Leukocytes Reduced 1 - Cryoprecipitate AHF	Donor eligibility (failure to defer donor with melanoma)	\$4,000	\$8,000
	B-0233-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/ Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
Northern Ohio 1573019	2004-042-0686603 B-2141-5 B-2142-5 B-2143-5 B-2144-5 B-2145-5 B-2146-5 B-2147-5	6 - Red Blood Cells 719 - Red Blood Cells Leukocytes Reduced 1 - Red Blood Cells Leukocytes Reduced Washed 50 - Red Blood Cells Apheresis Leukocytes Reduced 249 - Platelets Leukocytes Reduced 107 - Fresh Frozen Plasma 15 - Plasma	Donor eligibility (inadequate donor screening)	\$5,000 for each of 100 blood components	\$500,000
Pacific Northwest 3072996	2005-042-0931991 B-0158-6	1 - Platelets Pheresis Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
Penn-Jersey 2573021	2003-021-0223957 B-0492-5 2004-021-0292966 B-1407-5 2004-021-0308462 B-1426-5 2004-021-0346465 B-0479-6 B-0480-6 B-2037-4 B-2051-4 B-0819-5 B-0834-5 B-0835-5	1 - Red Blood Cells Leukocytes Reduced 1 - Red Blood Cells Leukocytes Reduced 1 - Red Blood Cells Leukocytes Reduced 1 - Red Blood Cells Leukocytes Reduced 5 - Platelets Pheresis Leukocytes Reduced 1 - Red Blood Cells Pheresis 1 - Red Blood Cells Pheresis 5 - Red Blood Cells Leukocytes Reduced Irradiated 6 - Platelets Pheresis Leukocytes Reduced Irradiated	Collection (sterility may have been compromised and failure to follow manufacturer's instructions) Donor eligibility (travel in malarial risk area) Donor eligibility (travel to malarial risk area) Donor eligibility (travel to malarial risk area) Component preparation (sterility may have been compromised and failure to follow manufacturer's instructions) Component preparation (sterility may have been compromised and failure to follow manufacturer's instructions) Collections (daily QC of Hematastat was unacceptable) Component preparation (discrepant irradiation times documented)	\$5,000 \$5,000 \$4,000 \$4,000 \$4,000 \$5,000 \$5,000 \$3,000 \$3,000	\$15,000 \$33,000 \$15,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	B-1434-5 B-1435-5	221 - Platelets Pheresis Leukocytes Reduced 27 - Platelet Pheresis Leukocytes Reduced Irradiated	Component preparation (monthly QC of pheresis products not performed)	\$3,000 for each of 100 blood components	\$300,000
	B-1531-5 B-1532-5	1976 - Platelets Pheresis Leukocytes Reduced 736 - Platelets Pheresis Leukocytes Reduced Irradiated 1635 - Fresh Frozen Plasma	Component preparation (manufacturer's instructions were updated but written procedures had not been updated)	\$4,000 for each of 100 blood components	\$400,000
	B-1533-5	1 - Red Blood Cells Leukocyte Reduced	Failure to control suspect blood component(s) (failure to quarantine components after receiving post donation information)	\$5,000	\$10,000
	B-1542-5 B-1543-5	1 - Fresh Frozen Plasma	Failure to control suspect blood component(s) (overweight units)	\$5,000	\$5,000
	B-1749-5	1 - Red Blood Cells	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	B-1881-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	B-1882-5	1 - Platelets Leukocytes Reduced	Donor eligibility (failure to defer donor for HIV risk)	\$5,000	\$5,000
	B-1906-5	13 - Platelets Pheresis Leukocytes Reduced	Storage/Shipping (shipment of products exceeded time allowed for shipping)	\$4,000	\$52,000
River Valley 1073003	2004-024-0324987 B-1759-5 B-1760-5	730 - Platelets Leukocytes Reduced 90 - Platelets Leukocytes Reduced Irradiated	Component preparation (low platelet yields)	\$4,000 for each of 100 blood components	\$400,000
South Carolina 1073009	2003-036-0157079 B-0965-6	1 - Red Blood Cells Leukocytes Reduced Irradiated	Donor eligibility (failure to defer donor for taking Lupron)	\$2,000	\$2,000
	2005-036-0859145 B-1009-6	5 - Platelets Pheresis Leukocytes Reduced	Storage/Shipping (time in transit not documented)	\$2,000	\$10,000
	2005-036-0978405 B-0921-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for lymphoma)	\$4,000	\$4,000
Southeastern Michigan 1873044	2004-013-0403966 B-1424-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2004-013-0652182 B-1425-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/ Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	2004-013-0514574 B-1454-5 B-1455-5 B-1456-5	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor eligibility (failure to defer donor for human T lymphotropic virus (HTLV) risk)	\$4,000	\$12,000
	2004-013-0588706 B-1483-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2005-013-0813171 B-2292-5 B-2293-5	1 - Red Blood Cells Leukocytes Reduced 1 - Fresh Frozen Plasma	Donor eligibility (failure to defer donor for taking Avodart)	\$5,000	\$10,000
	2005-013-0979194 B-0015-6	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2005-013-0948006 B-0038-6 B-0039-6	1 - Red Blood Cells Leukocytes Reduced 1 - Platelets Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$8,000
	2004-013-0414712 B-0124-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for HTLV risk)	\$4,000	\$4,000
Southern 1073000	2003-003-0268123 B-0445-6	3 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$12,000
	2003-003-0137009 B-0447-6	10 - Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (overweight unit)	\$5,000	\$50,000
	2003-003-0171218 B-0519-6	1 Red Blood Cells Leukocytes Reduced	Donor eligibility (travel in malarial risk area)	\$4,000	\$4,000
	2004-003-06555027 B-0736-6	1 - Platelets Pheresis Leukocytes Reduced	Component preparation (inappropriate release of unit with unacceptable platelet yield)	\$4,000	\$4,000
	2004-003-0362554 B-0737-6	1 - Platelets Pheresis	Component preparation (inappropriate release of unit with unacceptable platelet yield)	\$4,000	\$4,000
	2004-003-0508176 B-0762-6	1 - Platelets Pheresis Leukocytes Reduced	Component preparation (inappropriate release of unit with unacceptable platelet yield)	\$4,000	\$4,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/ Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	2004-003-0366103 B-0807-6	1 – Platelets Pheresis	Failure to control suspect blood component(s) (BDR questions related to HIV risk were unanswered)	\$5,000	\$5,000
	2004-003-0591717 B-0895-6	3 – Plasma Frozen	Failure to control suspect blood component(s) (inappropriate release after discovering clots in red blood cells)	\$5,000	\$15,000
	2004-003-0424198 B-0896-6	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (inappropriate release of unit with unacceptable platelet yield)	\$4,000	\$4,000
	2004-003-0577474 B-0947-6	2 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (product did not meet product specifications)	\$5,000	\$10,000
	2004-003-0339931 B-1008-6	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect blood component(s) (BDR high risk question unanswered)	\$5,000	\$5,000
Southern California 2072994	2003-006-0186567 B-0624-4	1 – Red Blood Cells Leukocytes Reduced	Storage/Shipping (product stored at incorrect temperature)	\$4,000	\$4,000
	2004-006-036788 B-1045-5	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$8,000
	2004-006-0360704 B-1049-5 B-1050-5	2 – Red Blood Cells 1 – Fred Frozen Plasma	Donor eligibility (failure to defer donor for body piercing)	\$4,000	\$12,000
	2004-006-0325150 B-1768-5 B-1769-5	5 – Platelets Pheresis Leukocytes Reduced 1 – Platelets Pheresis Irradiated	Component preparation (failure to perform product QC testing)	\$3,000	\$18,000
	2004-006-0321033 B-1910-5	1 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2003-006-0230785 B-0277-6	2 – Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$8,000

<u>Region/CFN</u>	<u>Biological Product Deviation Number/ Recall Number</u>	<u>Number of Recalled Products/Product Type</u>	<u>Reason for Recall</u>	<u>Penalty Amount Per Blood Component</u>	<u>Total Penalty Amount</u>
	2004-006-0375556 B-0672-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2003-006-01555824 B-0834-6	1 - Platelets Pheresis Irradiated	Failure to control suspect blood component(s) (inappropriate release-elevated platelet count)	\$5,000	\$5,000
	2004-006-0501165 B-1176-6	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
Southwest	2003-0490152156 B-1653-5	1 - Red Blood Cells Leukocytes Reduced 1 - Recovered Plasma	Donor eligibility (failure to defer donor for taking Proscar)	\$5,000	\$10,000
	2003-049-0226992 B-1680-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for low Hct)	\$3,000	\$3,000
	2004-049-0709793 B-1693-5	1 - Platelets Pheresis Leukocytes Reduced	Collection (sterility may have been compromised)	\$5,000	\$5,000
	2003-049-0182598 B-1699-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (failure to defer donor for unacceptable hemoglobin level)	\$3,000	\$3,000
	2004-049-0564594 B-1726-5	1 - Red Blood Cells Leukocytes Reduced	Donor eligibility (travel to malarial risk area)	\$4,000	\$4,000
	2004-049-0620192 B-1739-5	2 - Platelets Pheresis Leukocytes Reduced	Failure to control suspect blood component(s) (product intended for validation study)	\$5,000	\$10,000
	2005-049-0819904 B-0877-6	1 - Red Blood Cells	Donor Eligibility (BDR question pertaining to CJD was unanswered)	\$4,000	\$4,000
Western Lake Erie 1573020	2004-050-0305012 B-0082-6 B-0083-6 B-0084-6	1 - Red Blood Cells Leukocytes Reduced 1 - Cryoprecipitated, AHF 1 - Recovered Plasma	Donor eligibility (failure to defer donor for CJD risk)	\$4,000	\$12,000
	2004-050-0654999 B-1000-6 B-1001-6 B-1002-6	1 - Red Blood Cells Leukocytes Reduced 1 - Cryoprecipitated AHF 1 - Recovered Plasma	Donor eligibility (failure to defer donor for hepatitis risk)	\$4,000	\$12,000